

UNITED STATES DISTRICT COURT

DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION : Case No. 1:22-cv-00252-MSG
et al. :
Plaintiffs, :
v. : Philadelphia, Pennsylvania
: February 16, 2023
MODERNA, INC. et al. : 11:01 a.m.
:
Defendants. :
.

TRANSCRIPT OF INTITIAL PRETRIAL CONFERENCE HEARING
BEFORE THE HONORABLE MITCHELL S. GOLDBERG
UNITED STATES DISTRICT COURT JUDGE

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1 (Call to Order of the Court)

2 THE COURT: Hi, it's Mitch Goldberg. Mr. Cruz, are
3 we on the record?

4 THE DEPUTY CLERK: Yes, Judge.

5 THE COURT: Can't hear you.

6 THE DEPUTY CLERK: Yes, we are.

7 THE COURT: Okay. This is the matter of Arbutus
8 Biopharma Corporation and Genevant v. Moderna, Delaware matter,
9 22-252.

10 Who is on the phone for Arbutus? Am I pronouncing
11 that correctly? And could you identify who's going to be
12 speaking on behalf of the Plaintiffs?

13 DARALYN DURIE: This is Dar -

14 KAREN KELLER: Yes. Oh, go ahead, Daralyn.

15 MS. DURIE: I was going to say this is Daralyn Durie
16 from Morrison Foerster for Arbutus Biopharma.

17 THE COURT: And there was a lot of -- there's still
18 a lot of beeping. I don't know what that is. But I couldn't
19 hear you. Who was that?

20 MS. DURIE: I apologize. This is Daralyn Durie from
21 Morrison Foerster representing Arbutus.

22 THE COURT: And are you going to be speaking for
23 Arbutus?

24 MS. DURIE: To the extent that there are
25 Arbutus-specific issues, I would. But David Berl from

1 Williams & Connolly will be addressing the Court on behalf of
2 the Plaintiffs, collectively.

3 THE COURT: Okay. And do you want to identify
4 anyone else who's on the phone with you? You can if you want.

5 MS. KELLER: Yes, Karen Keller from Shaw Keller is
6 here on behalf of both Plaintiffs.

7 THE DEPUTY CLERK: Karen Keller.

8 THE COURT: Okay. Anyone else from Plaintiffs? I
9 know there's two Plaintiffs.

10 MS. DURIE: No, Your Honor. Just David Berl from
11 Williams & Connolly, and he might have Adam Harber with him, as
12 well.

13 THE COURT: Okay. How about Moderna?

14 BRIAN EGAN: Good morning, Your Honor. This is
15 Brian Egan from Morris, Nichols on behalf of Defendant Moderna.
16 Joining me on the call today are Pat Carson, Mark McLennan, and
17 Jeanna Wacker, all from Kirkland & Ellis.

18 THE COURT: Who's going to be speaking for Moderna?

19 MR. EGAN: Ms. Carson and Mr. McLennan will.

20 THE COURT: All right. We'd prefer one person. But
21 that's flexible. I invited the Department of Justice to
22 participate on the call. Is there a Lawyer from the Department
23 of Justice on the call?

24 GARY HAUSKEN: Yes, Your Honor. This is
25 Gary Hausken on behalf of the United States. And with me on

1 the call are Phillip Sternhel [phonetic], Hailey Dunn, and
2 Kavya Nagabuto [phonetic].

3 THE COURT: And it's Mr. Hausken? Okay.

4 MR. HAUSKEN: Yes, correct.

5 THE COURT: Your title is Director. What are you
6 Director, of the Civil Division, of -

7 MR. HAUSKEN: I am technically a Director of the
8 Commercial Litigation Branch. I am specifically the Director
9 of the Intellectual Property Staff.

10 THE COURT: Got it; all right. I have a couple
11 questions. I think the call was set up as a scheduling call.
12 But it may take a different route.

13 And let me just get my questions out there. So, the
14 first one is pretty basic, initially. So the first one is,
15 could someone from the Plaintiffs side explain to me the
16 business relationship between the two Plaintiff Entities,
17 Arbutus and Genevant?

18 DAVID BERL: Your Honor, would you like us to do
19 that now? Or do you want to enumerate all of your questions?

20 THE COURT: No, now, and just -

21 MR. BERL: Okay.

22 THE COURT: - one at a time, please.

23 MR. BERL: Yeah; so, the Arbutus is -

24 THE DEPUTY CLERK: Who's speaking?

25 MR. BERL: - the Patent -

1 THE DEPUTY CLERK: I'm sorry.

2 MR. BERL: Oh, this is David Berl for
3 Williams & Connolly -

4 THE DEPUTY CLERK: Thank you.

5 MR. BERL: - for Genevant. Arbutus is the Assignee
6 of the Patent, because they are the Patentee for the Patent in
7 this suit. And Genevant is an Exclusive Licensee with respect
8 to those Patents. And that's our -

9 THE COURT: Okay.

10 MR. BERL: - relationship.

11 THE COURT: And am I right that there are one, two,
12 three, four, five, six Patents in suit?

13 MR. BERL: That's correct, Your Honor.

14 THE COURT: Okay. So, as it relates to the
15 Government's Statement of Interest -- and I'm asking this
16 question for now only of Plaintiffs' Counsel -- I mean, first
17 tell me your view of this.

18 I mean, it was just filed a couple days ago. So
19 what's your overall view of the Statement of Interest of the
20 United States?

21 MR. BERL: Sure; thank you, Your Honor. This is
22 David Berl again from Williams & Connolly. In our view, the
23 submission from the Government respectfully doesn't change
24 anything that Your Honor held in its denial of the Motion to
25 Dismiss months ago.

1 The Holding that Your Honor had was that the "for the
2 Government" prong of the test under § 1498 should be subject to
3 discovery, that either Party can reraise the issue at Summary
4 Judgment, following that discovery.

5 But discovery should proceed as to that factual
6 question. And the Government's Statement of Interest provides
7 absolutely nothing new with respect to for the Government. In
8 that prong, there's no new -

9 THE COURT: Well -

10 MR. BERL: - facts that can be -

11 THE COURT: But doesn't it -- I'm sorry. I'm going
12 to interject questions. So sorry for the interruption. But
13 doesn't it present new information by way of the Contract that
14 they've got to -

15 MR. BERL: Well, we -

16 THE COURT: - leave out?

17 MR. BERL: So it presents two pieces of new
18 information, Your Honor, with respect to the Contract. And
19 that piece of information is relevant to the other prong of the
20 § 1498. There's the "authorization and consent" prong of the
21 Statute.

22 But the Government has nothing new to say, no new
23 information with respect to the "for the Government" prong.
24 What it argues, instead, is that -

25 THE COURT: Well, you're ahead of me. You're ahead

1 of me.

2 MR. BERL: Yeah.

3 THE COURT: The Ruling on the Motion to Dismiss was
4 framed. I'm going to really oversimplify it. But I think it
5 was framed in I have to view the Plaintiffs' Complaint in the
6 light most favorable. I mean, that's the classic
7 Iqbal/Twombly -

8 MR. BERL: Yeah.

9 THE COURT: - standard. But now the Government has
10 interjected a lot of details about what they said is a very
11 clear contractual relationship between them and Moderna, which
12 I don't think was considered in that Opinion.

13 So, I'm not sure I agree with your statement that you
14 say nothing's new. I mean, how? Isn't the Contract the
15 elephant in the room now? Isn't -- that is -

16 MR. BERL: Well, what -

17 THE COURT: - something that's completely new.

18 MR. BERL: Your Honor, there are two separate prongs
19 to the test. And Your Honor went through those prongs -- and
20 we think correctly -- in the denial for the Motion -- of the
21 Motion to Dismiss.

22 One prong is whether there was authorization and
23 consent by the Government. And indeed, the Contract is highly
24 relevant to that question, and the Government has now provided
25 more information as to the Contract that may be relevant to

1 deciding that prong of the test. Was there authorization or
2 any consent?

3 The second prong, which was the focus of Your Honor's
4 analysis, is whether the underlying infringement is for the
5 benefit of the Government. Is it for the Government, or is it
6 rather for the benefit of the United States population?

7 The Government has nothing to say on this question.
8 It's not a question for the Government to decide. It's a
9 question for the Court to decide.

10 That is a fiercely disputed factual issue. Moderna
11 says that the infringement is for the Government. Genevant and
12 Arbutus state that it's not for the Government.

13 Our Complaint says it's not for the Government. It's
14 the population. The part of the Contract that Moderna and the
15 Government don't want to talk about also says it's for the
16 Government and for the U.S. population.

17 And the only case that either side has cited,
18 including the Government now in its submission that actually
19 addresses facts similar to this, where the infringing article
20 is some medical treatment, takes the precisely opposite view
21 and holds that a medical intervention -- and that's what we
22 have here, a vaccine -- is not for the Government, but rather
23 for the population -- for the U.S. population.

24 And we submit that the Larsen case to which I'm
25 referring controls this inquiry. And the Government's -

1 THE COURT: Hold on. You're saying a lot. I want
2 to break it down a little bit. So, in your view -- I'm still
3 talking to Plaintiffs' Counsel. And I think it's Mr. Durie
4 [sic] who was speaking, right?

5 MR. BERL: Mr. Berl from Williams & Connolly,
6 Your Honor.

7 THE COURT: Berl, let me just -- Mr. Berl, okay.
8 Thanks, Mr. Berl. Do you -- can you in your view tell me, of
9 the six Patents in suit, putting aside your arguments as to who
10 it was -- who had benefited -- the Government or the general
11 population -- can you tell me of the six Patents in suit, is it
12 clear to you which one of those the Government is talking about
13 in their Statement of Interest? All, some, most?

14 MR. BERL: My understanding is that they're talking
15 about all of them, because all of them are directed to the
16 COVID vaccine that is the accused product in the case. And I
17 think the Government's view that they articulated was that they
18 provided authorization and consent with respect to that
19 product, which they procured in one Contract.

20 And I said a moment ago that there were two pieces of
21 information that were new in the Government's submission. One
22 of them was the Government's statement that it agrees with
23 Moderna that there's authorization and consent for the original
24 Contract between Moderna and the Government.

25 What the Government also said in its Statement of

1 Interest, which new to us and new, as far as I know, to the
2 Court, but not new to Moderna, is that, in a separate Contract,
3 entered into in July of 2022, the Government took out that
4 language, expressly denied that it had had authorization and
5 consent, and foreswore any liability with respect to that later
6 Contract.

7 THE COURT: Okay.

8 MR. BERL: Now, I would -

9 THE COURT: Mr. Berl, you keep -- I appreciate your
10 passionate advocacy. But you keep shifting the conversation to
11 issues I'm not ready to talk about yet.

12 I want to have a basic understanding and then get
13 more detailed. And you're in the more detailed land right now.
14 So just bear with me, okay?

15 MR. BERL: Okay.

16 THE COURT: So -

17 MR. BERL: Absolutely, Your Honor.

18 THE COURT: - is it your Client's view that -- do
19 you concede that your Patents that you claim are infringed, do
20 you concede that all of them are part of this Government
21 Contract?

22 In other words, did you -- there's a piece here, as I
23 understand it. The Government is saying, and probably Moderna,
24 that all of Moderna's product, including the use of the
25 delivery platform, was part and parcel of an overall Contract

1 with the Government.

2 And I'm asking. Was there any other separate entity
3 that you believe Moderna had a Contract with, where they used
4 your invention, like, I don't know, separate Contract with CVS
5 or Rite Aid or -

6 MR. BERL: Yeah.

7 THE COURT: - Walgreens?

8 MR. BERL: Yeah, so two observations on that,
9 Your Honor. One is that I think the Parties never disputed and
10 still don't dispute that there are accused sales of Moderna's
11 product that are, even in Moderna's view, not covered by
12 § 1498, the Government Contractor Defense.

13 That's why Moderna's Motion to Dismiss was not a full
14 Motion to Dismiss, but only partial Motion to Dismiss. And so,
15 there are additional sales that are not even allegedly part of
16 sales to the U.S. Government. And so, those are not implicated
17 at all under § 1498.

18 THE COURT: Okay.

19 MR. BERL: And -

20 THE COURT: So my understanding, then, is you're
21 saying all of the Patents -- the six Patents -- I won't name
22 them. We all know what they are. I took them from your
23 Complaint.

24 All of them, I agree -- this is you speaking -- seem
25 to be related to the Government's Contract that's at-issue.

1 But, there were separate sales involving some or all of those
2 Patents with other Entities, other than the Government. Did I
3 say that right?

4 MR. BERL: Correct, that's correct. And as we also
5 said -- and I want to make sure that this is clear -- even with
6 respect to the doses that were sold to the U.S. Government, we
7 allege acts of infringement.

8 That is use of the accused product that was not, in
9 any way, related to the U.S. Government, but rather used by
10 U.S. Citizens, used by those at private pharmacies like CVS,
11 that is not implicated by the Government's sales. That's a
12 separate argument that we advanced, even -

13 THE COURT: Right.

14 MR. BERL: - with respect to the Government's sales'
15 doses that the Government's Brief did not address.

16 THE COURT: As far as case -- I'm still talking to
17 Plaintiffs' Counsel with the understanding I'll give the other
18 Lawyers on the phone ample time to chime in. As far as case
19 management is concerned, Mr. Berl, I heard you say that this
20 issue of who benefited -- we can cabin it in that category --
21 who benefited, you're saying that's contested. And there needs
22 to be discovery on that.

23 Suppose at the end of the discovery, I determine --
24 and there's going to be -- I mean, I can't even envision what
25 the discovery's going to be. I mean, it could be the biggest

1 discovery project ever undertaken, or it could be -- it's
2 obvious who, at the end of the day, used the -- at least the
3 Moderna vaccine, the people who got needles in the arms, the
4 general population.

5 But there's only two questions. What happens if, at
6 the end of the day, I think this case should be in the
7 Claims Court and we've done voluminous discovery? I guess it
8 could be transferred there.

9 But how do I -- what's your recommendation on how I
10 manage all of this to make the Determination as to where the
11 case should be fully litigated? What's your -

12 MR. BERL: Yeah. And Your Honor, I think that goes
13 back to what I said earlier. This is not a full Motion to
14 Dismiss.

15 It's a partial Motion to Dismiss that is addressed to
16 only some of the sales, the sales to the U.S. Government,
17 pursuant to the first Contract. The second Contract that the
18 Government mentions in its submission, it says there's no
19 authorization and consent at all.

20 So no matter what happens in Your Honor's ultimate
21 Decision with respect to § 1498 and whether the Government
22 Contracting Defense applies to some of the doses, either way we
23 will be moving forward on the issues of infringement, whether
24 Moderna's vaccine infringed our Patents' validity to the extent
25 that Moderna can challenge validity, having failed in its

1 challenges before the Patent Office. And that's going to go
2 forward to trial, either way.

3 So if Your Honor decides to dismiss some of the sales
4 under \$ 1498 at Summary Judgment later on, then we will move
5 forward with a subset of the sales for purposes of trial. If
6 Your Honor does not -

7 THE COURT: Yeah, but then isn't there a risk?
8 Isn't there a risk at some point? And you can elaborate. And
9 I want you to specifically tell me your view on how to
10 intelligently manage this new issue that's in front of us.

11 But isn't there a risk that you're going to have two
12 Courts litigating liability issues? Let's just pick
13 infringement. I mean, and does that make any sense,
14 Claims Court and -

15 MR. BERL: It's the -

16 THE COURT: - the District Court?

17 MR. BERL: So it's not clearly, Your Honor, that
18 that would happen. Even if Your Honor were to dismiss some of
19 the Claims at Summary Judgment after discovery, and so we'd
20 move forward to trial before Your Honor with respect to the
21 Government sales from the July '22 Contract and otherwise, and
22 sales not to the U.S. Government and any uses by
23 Private Entities.

24 And then, at some point, we could file a lawsuit in
25 that scenario against the Government. It's not clear that the

1 issues of validity and infringement would be relitigated.

2 There would be no need to do that.

3 Often, that's not the case. And the only issue,
4 then, going forward, if we were to prevail before Your Honor
5 and then potentially even on appeal, with respect to the
6 infringement and validity issues, the question to be
7 adjudicated by the Court of Claims at that point would be:
8 what money is owed to Plaintiffs by the U.S. Government, in
9 connection with whatever sales Your Honor has ruled should be
10 collected from the Court of Claims, rather than in this
11 litigation?

12 But I don't think the efforts would be duplicative.
13 And to the extent that we move forward, as we've already begun
14 into discovery on validity, on infringement, on damages, all of
15 that discovery will need to happen without respect to how
16 Your Honor ultimately rules on the "for the Government" prong
17 under § 1498, because we're -

18 THE COURT: So is it your view that this Statement
19 of Interest filed by the Government should just be folded into
20 a Discovery Schedule, and I should move forward? And there
21 should be discovery.

22 And at the end of the day, if some of the cases
23 should be in the Claims Court, so be it. But, we shouldn't
24 pause. We should just move forward with discovery. Is that
25 what you're saying?

1 MR. BERL: Absolutely, absolutely, Your Honor.
2 That's how I interpreted your Order a few months ago. And the
3 Government has now weighed in.

4 What they say, as I said, it's pertinent to one of
5 the two prongs of the test that Your Honor addressed, which is
6 the authorization and consent. I don't think it's relevant, at
7 all, to the "for the Government" prong of the test. And I
8 disagree with their legal analysis to the contrary.

9 And there is discovery to be taken, as Your Honor
10 observed, including whether Moderna was under the Government's
11 control in connection with the development and testing of its
12 vaccines, and its decision to use our invention in its vaccine.

13 The cases ask the question under the § 1498 test:
14 was the Defendant, here Moderna, acting under the Government's
15 control? Or was it acting as its own Entity in designing the
16 infringing product?

17 And that's a question Your Honor asked before. What
18 kind of discovery do we want? That's the kind of discovery we
19 want.

20 What was the contractual relationship between the
21 Government and Moderna? And at what level was the Government -

22 THE COURT: Well, you have the Contract, right? You
23 have most of it. I think some of it's redacted. But, I mean,
24 don't you have the Contract?

25 MR. BERL: We have the ultimate Contract. But we

1 don't have all the communications. We don't have any
2 information about whether the Government exerted control over
3 the design of the vaccine, which lipids to use, which ratio to
4 use, which was a core issue on infringement in our case.

5 Was the Government controlling Moderna's development
6 such that what Moderna was doing was for the benefit of the
7 Government, under the control of the Government? Or was
8 Moderna acting independent of the Government in developing its
9 vaccine and making these decisions in order to sell the product
10 ultimately to the Government for the benefit of the
11 U.S. population? And it was deciding how to develop its
12 vaccine and design its vaccine in a way that infringed, without
13 regard to Government input. We don't know the answers to any
14 of those questions.

15 THE COURT: Yeah, I get it.

16 MR. BERL: But -

17 THE COURT: Okay. I understand. Explain to me the
18 difference in your available remedies in the District Court
19 versus the Claims Court.

20 MR. BERL: Our -

21 THE COURT: Explain to me how they're different.

22 MR. BERL: Yeah, the -- so our available remedies in
23 the District Court, as Your Honor knows, would be damages under
24 § 284 and what we're seeking here is a reasonable royalty.
25 There is available, in District Court, of course, exceptional

1 damages and enhanced damages. And we are seeking those
2 damages.

3 Before the Court of Claims, the U.S. Government's
4 payment is simply a reasonable royalty analysis. There is no
5 enhanced damages, willful infringement damages before the Court
6 of Claims.

7 THE COURT: Okay. All right. I want to ask --
8 thank you -- I want to ask Moderna's Counsel some questions.
9 And the first one will be along the same lines, which is, given
10 the Statement of Interest filed by the United States on the
11 14th, what is your view as to how the schedule should -- what
12 should the schedule look like going forward?

13 MARK MCLENNAN: Good morning, Your Honor. This is
14 Mark McLennan for Moderna. Our view is that the Government's
15 Statement of Interest entirely resolves the outstanding issues
16 from Your Honor's Opinion on Moderna's Motion to Dismiss.

17 And that both "for the Government" prong and the
18 authorization and consent, the Government has explicitly
19 confirmed that a Contract was made for the benefit of the
20 Government, and with its authorization and consent.

21 We think now the Motion to Dismiss could be disposed
22 of. And the sales pursuant to that -

23 THE COURT: Well, that's your view. And that's the
24 Government's view. I've never really seen a Statement of
25 Interest like this before. So, I'm going to say -- I think

1 correctly -- the Government's not a Party.

2 So, your view, okay, I get it. But the Plaintiffs
3 don't agree with you. So I mean, you're not suggesting I
4 should just take the Statement of Interest, reverse myself, and
5 send the case to Claims Court, are you?

6 MR. MCLENNAN: Your Honor, I think if Your Honor was
7 reconsidering the Decision on the Motion to Dismiss, or if you
8 want additional briefing, I think that is a possibility. The
9 Statement of Interest in this case is providing information on
10 both prongs.

11 And the Courts have looked to the Government's
12 Statement on both prongs and found that to be persuasive. So,
13 it will be in line with other cases.

14 THE COURT: And when I read those other cases, the
15 Government's Statement is accepted without question by a Court.
16 Is that what you're saying?

17 MR. MCLENNAN: No, Your Honor, sorry, not accepted
18 without question. But it was considered persuasive towards
19 whether those elements are met.

20 THE COURT: Okay. Persuasive, but, I mean, who
21 would bear the burden in this?

22 MR. MCLENNAN: So, Your Honor, Moderna still bears
23 the burden and we have to prove it, based on the allegations of
24 the Complaint accepted as true, and other matters before it.
25 The Government's Statement has been considered in other

1 contexts under § 12(b)(6), like the IRS Corp. v. Japan
2 Airlines, which was cited in the Statement of Interest and in
3 Your Honor's Opinion.

4 THE COURT: Um-hmm.

5 MR. MCLENNAN: So it would be a matter that could be
6 considered in deciding the Motion to Dismiss.

7 THE COURT: So it sounds like you're saying to me,
8 procedurally, what should happen -- and I don't want to put
9 words in your mouth. You tell me what you think is best.

10 But what should happen is I should reconsider the
11 original Ruling, which was based on a § 12(b) -- I think a
12 § 12(b) Motion to Dismiss, in light of the Government's
13 Statement of Interest, new information, and reconsider it. If
14 that's right, are you saying with or without discovery?

15 MR. MCLENNAN: Your Honor, we think it could be
16 resolved, based on the Statement of Interest, alone. The
17 Government's affirmatively stated that it was for their benefit
18 with an authorization and consent. We don't think any
19 discovery will be needed.

20 THE COURT: Okay. What's the -- I got to dig into
21 these cases a little more, if we're going to reconsider it.
22 But initially, my impression was the cases at least cited in
23 the Statement of Interest -- cited in the Statement of Interest
24 pertain to situations involving wartime decisions. So, do you
25 have cases that pertain to situations like this?

1 MR. MCLENNAN: We do. I think, Your Honor, you
2 might be thinking of the Larsen case, which Plaintiffs took you
3 back to for the medical splits.

4 I think the only similarity between Larsen and this
5 case is that they're both in the medical context. But that's
6 where the similarities end.

7 In that case, the Government was actually the
8 Defendant. And the Government opposed the Application of
9 § 1498.

10 It wasn't a situation like what we have here, where
11 the Government is affirmatively taking the position that it was
12 done for their benefit and with their authorization and
13 consent.

14 THE COURT: Okay.

15 MR. MCLENNAN: That's why the Court looked to
16 discovery in that case, because there was no statement there,
17 like what you have here.

18 THE COURT: Got it; I just want to make sure. I'm
19 99-percent sure I know the answer. But however we get there,
20 if I were to send the whole case to the Claims Court, you're
21 still going to contest liability, right? You will?

22 MR. MCLENNAN: Your Honor, so we would no longer be
23 the Defendant. It would be against the Government. So I don't
24 want to speak to -

25 THE COURT: Okay.

1 MR. MCLENNAN: - what the Government would do in
2 that instance. But just to go back to one of your earlier
3 questions about, where should we go from here, the purpose of
4 § 1498 was to relieve Contracted Entities, like Moderna, from
5 liability and prevent them being caught up in litigation.

6 And so, for us to proceed through discovery, or
7 towards the end of the case, and then for it to be litigated
8 again in the Court of Federal Claims is duplicative and it
9 undermines the purpose of § 1498.

10 THE COURT: It's what? I'm sorry. What?

11 MR. MCLENNAN: Duplicative and would undermine the
12 purpose of § 1498.

13 THE COURT: What is duplicative? What do you mean
14 by that?

15 MR. MCLENNAN: It would essentially be successive
16 litigation. So, Moderna would be forced to go through
17 discovery here. And -

18 THE COURT: Right.

19 MR. MCLENNAN: - as Plaintiffs noted, we're only
20 moving to dismiss part of the Complaint, so only some of the
21 sales.

22 THE COURT: Right.

23 MR. MCLENNAN: Plaintiffs are -

24 THE COURT: Right.

25 MR. MCLENNAN: - already seeking extensive discovery

1 into every single batch that was made. They want detailed
2 records and testing, and analysis of every batch that was made.
3 They're also looking for detailed records and discovery.

4 THE COURT: Yeah, you don't have to -- I don't want
5 you to list everything that Plaintiffs is asking for. I would
6 observe, though, that if the right way to get to the answers is
7 discovery, I'm just thinking having Moderna do duplicative
8 discovery would not be kind on my reasons to forego the most
9 intelligent route to get to the right answers to this.

10 So let me ask Mr. Hausken. So, as I understand it --
11 and I'm just looking at understanding the Statement of Interest
12 concept, Mr. Hausken -- is Counsel for Moderna right?

13 Do you -- if this goes to the Claims Court, are you
14 essentially with the Defendant accused of infringements in that
15 court? Is that how conceptually this would work?

16 MR. HAUSKEN: That is correct, Your Honor. The
17 Government becomes the Defendant in all cases in this Court of
18 Federal Claims.

19 THE COURT: Um-hmm.

20 MR. HAUSKEN: And so, it would be against the
21 United States. And certainly any Judgment is paid by the
22 United States.

23 THE COURT: And your intention is to contest
24 infringement, right?

25 MR. HAUSKEN: No, at this point in time, Your Honor,

1 we are not sufficiently familiar that I could say that
2 affirmatively. But it is generally our practice to investigate
3 the case thoroughly. And if there are defenses, to raise those
4 defenses before the Court.

5 THE COURT: Okay. Do you want to comment,
6 Mr. Hausken, on any discussions that we've had thus far?

7 MR. HAUSKEN: I guess there's two points that I
8 would just like to mention. One is I don't think that the --
9 well, I think that the "for the benefit" aspect of the inquiry
10 is, in fact, a question for the Government. And certainly we
11 have, I think, answered that in our Statement of Interest.

12 The other point that I would like to respond to is
13 Plaintiffs suggested that a question of -- there's a question
14 of whether Moderna was acting under the Government's control in
15 manufacturing the product.

16 And that is not a question for authorization and
17 consent, or for § 1498, generally. That's a question that is
18 pertinent in cases of implied authorization and consent.

19 Here, we have express authorization and consent. And
20 therefore, whether there's control or not is not an issue. We
21 have given our consent. The Government has given its consent
22 to the Contractor and that should end the inquiry.

23 THE COURT: Well, what about the point Mr. Berl is
24 making as to the benefit? How?

25 MR. HAUSKEN: The -

1 THE COURT: Is that said and done, just because the
2 Government and Moderna says so?

3 MR. HAUSKEN: Well, treading a fine line here,
4 Your Honor. But certainly the Court always has a role in
5 determining whether § 1498 applies, because it has been held to
6 be an affirmative defense.

7 That said, I think there's two factors here that are
8 pertinent. One is that this is an express Contract for the
9 purchase of vaccine to be distributed to the public.

10 The purpose of that Contract and the fact that it
11 used some \$8 billion in Government funding, I think,
12 demonstrates that there was a benefit to the Government, in
13 general.

14 I would also point the Court, however, to our
15 analysis under Severson Engineering and also believe it is
16 ASCD, the Advanced Software. Severson suggested that where you
17 have a Contract like this that the benefit to the Government is
18 apparent. And essentially the inquiry gets down to whether the
19 Government has granted its authorization and consent.

20 ASCD, Advanced Software, I think, is important, in
21 particular because trial to the Court is the ultimate Arbiter
22 and Decisionmaker here. The Federal Circuit has looked clearly
23 to the Statement of Interest, or, in the case of ASCD, to the
24 Statement of Counsel before the Court, and relied on those as
25 demonstrating that there was authorization and consent, and

1 that it was for the benefit of the Government. So, I think you
2 can look at that. Well-beyond that, I think -

3 THE COURT: I'm sorry. Could you go back to what
4 you said?

5 MR. HAUSKEN: Sure.

6 THE COURT: I missed the last sentence-or-two.

7 MR. HAUSKEN: In Advanced Software, the situation
8 was that there was -- it was kind of a little bit of confused.
9 The Government had granted authorization and consent to a
10 letter.

11 And then, there was a question before the Court as to
12 whether that was sufficient. And the Federal Circuit said that
13 even Counsel's statement to the Court that confirmed the
14 authorization and consent was sufficient for the Government to
15 invoke § 1498 and authorization and consent.

16 And it's not a one part for the Government to do and
17 the benefit for the Court to determine separately. It is a
18 two-part test that decides whether § 1498 applies.

19 So, the Court found in Advanced Software that where
20 the Government comes in and confirms its authorization and
21 consent, that is a strong indicator. Now, the Court has never
22 gone so far as to say that -- and should never go so far as to
23 say that District Courts don't have authority to make a -- I
24 guess, a contrary Decision. But certainly it should be a
25 strong indicator of the authorization and consent.

1 THE COURT: Understood; I'm going to put you on hold
2 for a second. I want to look at some notes. I think I have a
3 couple other questions, okay?

4 MR. HAUSKEN: Certainly.

5 THE COURT: All right, hold on.

6 (Asides)

7 THE COURT: I'm back. I have a couple other
8 questions. Does Moderna concede that, if I were to completely
9 agree with their position, that there would still remain some
10 portions of this case in the District Court of Delaware?

11 MR. MCLENNAN: Yes, Your Honor. That's correct.
12 It's only -

13 THE COURT: So -

14 MR. MCLENNAN: - a partial Motion.

15 THE COURT: - why wouldn't -- then why would I --
16 and maybe you haven't suggested I do this. And the portion
17 that would remain with me would be the issues that I thought
18 were teed-up, infringement, right? I guess you have a validity
19 argument. Why would it be a good idea for me to stay the
20 matter in any way and not let Plaintiffs go ahead with their
21 infringement discovery?

22 MR. MCLENNAN: Well, I mean, Your Honor, just to be
23 clear, they would go ahead with their infringement discovery.
24 We're not -

25 THE COURT: Okay.

1 MR. MCLENNAN: - saying they wouldn't on the
2 remaining Claims. It's just the infringement inquiry would be
3 limited to the doses that are left in the case, not to the
4 batches that were sold to U.S. Government.

5 THE COURT: Great, okay. That's what I wanted to
6 clarify. So you're saying send whatever port -- and I'm not
7 clear on what portion you want me to send to the Claims Court.
8 And for purposes of the discussion, I don't think I need to
9 drill down that far.

10 But, you're saying send the appropriate portions of
11 the case, based on the Statement of Interest, to the Court of
12 Claims. And we can start with the discovery on infringement in
13 whatever piece is left in the Federal Court, right?

14 MR. MCLENNAN: Yes, that's correct, Your Honor. And
15 if it helps to conceptualize it, what we're essentially asking
16 to be dismissed are any sales that were made pursuant to that
17 B-100 Contract that -

18 THE COURT: Yeah.

19 MR. MCLENNAN: - had the authorization to move
20 forward.

21 THE COURT: Okay.

22 MR. MCLENNAN: Everything else remains in the case.

23 THE COURT: Right; yeah. That's a hugely general
24 delineation. I get it. What the sales are that would go to
25 the Claims Court, I'm not prepared enough to figure that out

1 right here and now.

2 Okay. So, question for Plaintiffs' Counsel, then:
3 don't you want to weigh-in? Do you want to weigh-in on this
4 Statement of Interest and respond to the cases that have been
5 cited? I mean, if you want to do that, I guess, and
6 simultaneously litigate the cases that remain in Delaware,
7 right?

8 MR. BERL: Absolutely, Your Honor. We disagree with
9 personally everything the Government said with respect to its
10 legal analysis.

11 I'm happy to submit something reflecting that. But
12 Your Honor indicated before in his denial of the Motion to
13 Dismiss that he disagreed with the reading of -

14 THE COURT: Yeah, I'm sorry.

15 MR. BERL: So -

16 THE COURT: Excuse me. I wasn't asking you to argue
17 the point.

18 MR. BERL: Sure.

19 THE COURT: I was asking you, do you agree with the
20 premise that I think we're all agreeing on? You get to
21 litigate your case.

22 You get to do discovery on what remains here. And
23 you want to -- the opportunity to be heard on the Government's
24 Statement of Interest, right?

25 MR. BERL: Correct, Your Honor. I don't think

1 there's a Motion pending right now. I suppose -

2 THE COURT: Oh, no. No, it's teed-up. It's
3 teed-up. I mean, the Statement of Interest sort of tees up the
4 issue.

5 I mean, procedurally, if everyone thinks there needs
6 to be a Motion, maybe it's best, given the magnitude of the
7 case that we will do some type of Motion. But what I was going
8 to suggest is I started to look at the Proposed Scheduling
9 Orders that the Parties have submitted. And then, the
10 Statement of Interest was dropped in, which sort of shifted my
11 focus.

12 So, I think what we should do is have a real quick
13 turnaround. I'm talking about a couple weeks. I'll accept
14 letters, maybe no more than 10 pages -- I'm just sort of
15 thinking out loud -- from each side.

16 And I'll let the Government weigh-in if they want, as
17 well, on how the case should not proceed procedurally now that
18 we have this new piece of information. And just get some
19 letters from you.

20 And then, go back to the drawing board and decide how
21 I'm going to set the schedule up, which will either keep the
22 case here all the way and reject Moderna and the Government's
23 position, or keep all the case here and send it all to the
24 Claims Court, or someplace in between.

25 So, that's my suggestion: couple week turnaround;

1 10-page letters; all three sides. Plaintiff, what's your view?

2 Does that work for you?

3 MR. BERL: That works, Your Honor. Just to clarify,
4 we've already started down the road to discovery. As I think
5 Moderna has agreed, that discovery about infringement and
6 validity would continue in any event. I don't want to lose -

7 THE COURT: Yeah.

8 MR. BERL: - the benefit of -

9 THE COURT: No, I'm not -- given Moderna's statement
10 that they agree that some of the case is going to stay here no
11 matter what, I'm not going to stay all discovery, if that's
12 where you were going.

13 MR. BERL: Yes, Your Honor.

14 THE COURT: Okay. Other than that, you're good,
15 Mr. Berl?

16 MR. BERL: Yes, Your Honor. Thank you.

17 THE COURT: All right. And Counsel for Moderna?

18 MR. MCLENNAN: Your Honor, that's -

19 THE COURT: Just a follow-up letter, is that good
20 with you?

21 MR. MCLENNAN: That's excellent, Your Honor. Thank
22 you.

23 THE COURT: Okay. And Mr. Hausken, do you want to
24 weigh-in?

25 MR. HAUSKEN: We would, I guess, welcome the

1 opportunity to respond to the -- anything that's offered, just
2 to make -

3 THE COURT: No, I don't want to get into the you'll
4 look at what they -- I want these filed simultaneously -

5 MR. HAUSKEN: Oh.

6 THE COURT: - because I want to make that -

7 MR. HAUSKEN: Okay.

8 THE COURT: - Decision. You know what they're going
9 to say.

10 MR. HAUSKEN: Yeah, I think our -- if that's the
11 case, Your Honor -- I think our Statement of Interest will
12 probably answer all the arguments -

13 THE COURT: Yeah.

14 MR. HAUSKEN: - as it is.

15 THE COURT: Okay.

16 MR. HAUSKEN: So -

17 THE COURT: That's -

18 MR. HAUSKEN: I will make it as simple for the
19 Court.

20 THE COURT: Okay. Thanks. I think your Statement
21 of Interest is pretty comprehensive. So I appreciate that.
22 And because of your reasonableness, you'll be served with
23 copies of the letters. I think you should get them.

24 And if you have a good-faith basis to say, Judge, I
25 thought what we submitted was enough, but I want to add a

1 couple things, then you can let me know. And I'll probably let
2 you do that. Okay?

3 MR. HAUSKEN: Thank you, Your Honor.

4 THE COURT: Okay. All right. I think, then, that's
5 what we're going to do. And so, that was very helpful. And
6 does anyone else want to say anything?

7 I mean, we are going to take it here one step at a
8 time. But I want to turn it around quickly. So I'm going to
9 give you two weeks to do this.

10 All right. So let's just wrap it up there, because I
11 got to actually go. So I'll issue that Order and we will go
12 from there. Okay?

13 MR. BERL: Thank you, Your Honor.

14 THE COURT: Okay.

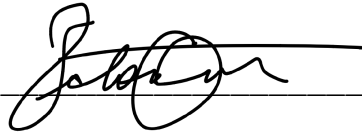
15 MR. MCLENNAN: Thank you, Your Honor.

16 THE COURT: Thank you, everyone. Take care.

17 (Proceedings concluded at 11:47 a.m.)
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C E R T I F I C A T I O N

I, VICTORIA O'CONNOR, court-approved transcriber,
certify that the foregoing is a correct transcript from the
official electronic sound recording of the proceedings in the
above-entitled matter.



Victoria O'Connor, CET

February 20, 2023

Date

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